JAN 1 8 2006

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K053259

1. Submitter:
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   Date of Summary: Jan 5, 2006

2. Name of Device
   Disposable PVC Examination Glove, Powdered and Powder-free

3. Predicate Device Information
   (1) Powder-free Vinyl Examination Gloves
   Bernard Technologies, Inc.
   K-number: K033229
   (2) Pre-Powdered Non-Sterile Vinyl Examination Glove
   Shangdong Perfect Plastic Co., Ltd
   K-number: K042213

4. Device Description:
   Class I powder-free patient examination glove LYZ, meets all of the requirements of ASTM Standard D5250-00E1. Class I powdered patient examination glove, LYZ, also meets all the requirements of ASTM Standard D5250-00E1, as well as all the requirements of ASTM Standard D6124-01 for powdered glove and its residue powder.

5. Intended Use
   A patient examination glove, either powdered or powder-free, is a disposable device intended for medical purposes that is worn on the hand of healthcare and other personnel to prevent contamination between healthcare personnel and the patient's body.

6. Comparison to predicate device:
Practical Protective Plastic Manufactory, Ltd. Disposable PVC Examination Glove, Powdered, and Powder-free, are substantially equivalent in safety and effectiveness to the Pre-powdered Non-sterile Vinyl Examination Glove, from Shandong Perfect Plastic Co., Ltd., and the Powder-free Vinyl Examination Glove of Bernard Technologies, Inc. This conclusion was established based on the Non-clinical tests, and by being brought in conformance with the Standard of ASTM D 5252-00E1.

7. Conclusion:
Practical Protective Plastic Manufactory, Ltd. Disposable PVC Examination Gloves, Powdered, and Powder-free, are substantially equivalent in safety and effectiveness to the legally marketed gloves on the US market: Pre-powdered Non-sterile Vinyl Examination Glove from Shandong Perfect Plastic Co., Ltd., and the Powder-free Vinyl Examination Glove of Bernard Technologies, Inc. It also conforms to ASTM D5250-00E1 standards, as well as applicable 21 CFR references, and, meets pinhole FDA requirements, biocompatibility requirements and labeling claim requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2006

Practical Protective Plastic Manufactory Limited
C/O Ms. Laura Danielson
Responsible Third Party Official
TÜV America, Incorporated
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

Re: K053259
Trade/Device Name: (Mutiple Brand Name) Disposable Vinyl Patient Examination Gloves, Powdered and Powder-Free
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: January 3, 2006
Received: January 9, 2006

Dear Ms. Danielson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Applicant Name: Practical Protective Plastic manufactory, Ltd.

Device Name: (Mutiple Brand Name) Disposable Vinyl Patient Examination Gloves, Powdered and Powder-free

K-Number: Pending K053259

Indications for Use:

A patient examination glove is a disposable device intended for medical purposes that is worn on the hand of healthcare personnel to prevent contamination between healthcare personnel and the patient's body, fluids, waste or environment.

Prescription Use_____.
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ✓.
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

1/12/06

[illegible], General Hospital,
[illegible] Dental Devices

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